

Health

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Managing the financial implications of NICE guidance

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Summary

The National Institute for Health and Clinical Excellence (NICE) was created to promote high clinical standards and equitable provision of clinical care in the National Health Service (NHS). This is primarily achieved by issuing guidance to the NHS in the form of technology appraisals (for example, assessments of new drugs such as etanercept for rheumatoid arthritis) and clinical guidelines (for example, treatment and management of chronic heart failure), both of which are based on clinical and cost-effectiveness criteria. Once implemented by healthcare providers, this guidance plays a crucial role in the delivery of high-quality and equitable patient care. From 1 April 2005 NICE's remit has expanded to include public health guidance.

Implementation of NICE guidance

Currently, the implementation of NICE guidance by NHS bodies is less comprehensive and timely than desired. Our research identified that technology appraisals issued by NICE (which the Department of Health (DH) directs the NHS to fund within three months of publication)¹ tend to be implemented more consistently across the NHS, compared to clinical guidelines. The NHS is normally required to fund technology appraisals within three months of publication, but do not always achieve this, particularly where there are high capital costs or the appraisal involves expensive drugs or prostheses.

Implementation of clinical guidelines, was much more variable in the organisations taking part in our survey. Guidelines (to which the funding direction does not apply) can require substantial changes to local care pathways often involving both primary and secondary care, which makes implementation more complex.

The introduction of the Healthcare Commission's *Annual Health Check*, which will apply to NHS bodies from 2005/06, includes a standard on conforming to NICE technology appraisals and taking clinical guidelines into account when planning and delivering treatment or care. This will provide additional incentives to implement NICE guidance and is expected to further improve implementation rates for technology appraisals in particular.

¹ *Directions to Primary Care Trusts and NHS Trusts in England Concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE)*, Department of Health, 2002.

Funding

The availability of funds to implement guidance can clearly be a factor in implementation. NICE guidance usually, but not always, requires additional expenditure. The estimated cumulative total cost to the NHS of implementing health technology appraisals between 1999-2004 was £800 million,^I which represents approximately 1 per cent of total NHS expenditure. Although there is a funding direction for technology appraisals, and the DH includes estimated costs for NICE guidance in PCT allocations, competing local priorities, or financial constraints, may mean that individual primary care trusts (PCTs) sometimes consider whether they fund more expensive guidance (such as etanercept and infliximab for rheumatoid arthritis, which have recently received attention)^{II} from their allocations.

Until recently, the implementation of NICE guidance has relied on local negotiation between commissioners and providers to identify and release funding for specific appraisals and guidelines, covered through PCT general allocations from the DH. The introduction of payment by results (PbR), the new system of funding services, impacts on the funding of NICE guidance. A national tariff structure has been established, which will eventually cover most acute sector activity. However, not all guidance is currently reflected in the tariff (for example some high-cost drugs are excluded) and consequently, funding for the implementation of this guidance will still need to be negotiated between commissioners and providers.

Role of financial management

This report outlines a number of key financial management steps that should be undertaken when implementing NICE guidance. These include:

- identification of relevant guidance (both current and forthcoming) and assessing extent of compliance;
- verifying whether guidance is covered within the tariff under PbR;

^I Internal estimate from NICE, 2005.

^{II} *Access to Anti-TNF Alpha Therapies for Adults with inflammatory arthritis*, British Society for Rheumatology & Arthritis and Musculoskeletal Alliance, 2005.

- development of the business case, including an assessment of the costs and savings associated with the guidance;
- confirming funding arrangements for implementation of guidance;
- incorporating guidance into financial plans;
- budgeting; and
- monitoring implementation, costs and savings.

Weaknesses in financial management

This study, undertaken in conjunction with NICE, found that while funding was perceived as the biggest barrier to the implementation of NICE guidance, the most significant issue we identified was weaknesses in local financial management arrangements. Although NHS trusts and PCTs show a high level of awareness of existing or forthcoming NICE guidance, we identified the following weaknesses in current arrangements:

- Horizon scanning to identify future NICE guidance and to assess the financial implications for the organisation is not systematically undertaken. Only 26 per cent of NHS bodies participating in this study regularly undertake horizon scanning to assess the financial impact of forthcoming guidance on the organisation.
- NHS bodies do not routinely identify costs and savings associated with guidance, or do not use robust costing methodologies, making it more difficult to assess financial impact and affordability. Only 30 per cent and 36 per cent of study participants identified savings for clinical guidelines and technology appraisals respectively. 76 per cent and 68 per cent of respondents identified costs for clinical guidelines and technology appraisals, however the quality of these calculations were not robust and tended to be generic costings, rather than accurate assessments.
- Cost templates recently developed by NICE to accompany clinical guidelines are not always used locally, and awareness about the existence of cost templates needs to improve. Only 20 per cent of respondents had used the template for fertility treatments, a further 20 per cent did not know of its existence.
- Implementation of NICE guidance is not routinely integrated into financial planning and budgeting processes. Action plans for implementation of the guidance are not always reflected in financial plans. The study found that only 24 per cent and 12 per cent of NHS bodies always produced an action plan for clinical guidelines and technology appraisals respectively.

- The use of business cases to formalise arrangements for implementation of NICE guidance is the exception rather than the rule.

Payment by results

Many PCTs and trusts are unclear as to how PbR will affect the funding of NICE guidance, and there are unrealistic expectations that PbR will address perceived funding limitations. NHS bodies need to be clear about which guidance is covered in the tariff, and which still requires separate funding. Where the cost of NICE guidance is included within the tariff, PCTs will expect providers to deliver accordingly without additional funding. Under PbR the risks associated with managing the costs of implementing guidance included in the tariff will therefore transfer from commissioners to providers. Funding of NICE guidance may be less clear locally than in the past, as the current local process for PCTs is often to set aside specific sums for implementation of NICE guidance.

Monitoring implementation of NICE guidance

Under the new performance assessment system, *The Annual Health Check*, NHS bodies will be required to make a declaration about whether they are conforming with NICE technology appraisals standards and taking clinical guidelines into account when planning and delivering treatment of care. Non-compliance with technology appraisals will impact on performance assessment and therefore represent a greater risk to the organisation. NHS bodies will not be able to complete this declaration without having robust systems in place to assess and plan for the financial impact associated with implementation of NICE guidance and to monitor progress. However, this is something that, to date, most organisations have been struggling to achieve.

Recommendations

Implementation of NICE guidance is not always straightforward and comprehensive implementation of all guidance across the NHS may not be possible as there may be competing priorities for funding locally. However, individual NHS bodies could significantly improve local implementation by strengthening their financial management arrangements. NHS bodies need to be aware of how much NICE guidance will cost to implement, assess whether it is affordable by considering it alongside other competing priorities and then include it within their financial plans. In summary, consideration of the financial aspects of implementing NICE guidance needs to be integrated into mainstream financial management arrangements.

NHS bodies should already have procedures in place to support the implementation of NICE guidance, and it is vital that these procedures also consider the impact on the finances of the organisation. Having a formal policy that incorporates financial management arrangements contributes to the delivery of the quality and equity that NICE was created to promote. This, in turn, will help deliver the consistent and comprehensive implementation of NICE guidance across the NHS and help NICE achieve its objectives to reduce variations in prescribing practice, improve equity of clinical care and raise the quality of patient care.

Our key recommendations are:

- Horizon scanning of NICE guidance should be undertaken systematically by NHS bodies. Draft guidance should be consulted to assess the current level of compliance and likely financial impact of implementation. This function can be shared across NHS bodies locally.
- NHS bodies should develop a clear understanding of what guidance is inside and outside the tariff and ensure that this understanding is consistent with other local bodies. Where guidance falls outside the PbR tariff, NHS bodies should undertake the appropriate negotiations to ensure that funds are provided to implement the guidance. These negotiations should cover all costs associated with implementation of the guidance, including capital costs.
- NICE, in conjunction with the DH PbR team, should indicate at draft stage, if guidance is likely to be inside or outside of the tariff, which will help with financial planning for the implementation of guidance.
- Cost templates should be used where available to estimate the costs of NICE guidance to the local health community.
- NICE should undertake activities to raise the awareness of cost templates and promote their use within NHS bodies.
- Relevant members of the finance team should be closely involved in the implementation process for NICE guidance at the appropriate stages.
- Where guidance is not implemented, NHS bodies should list this on a risk register that is shared between trusts and PCTs.
- PCTs should develop a system of monitoring to ensure that services paid for under PbR are provided, with individual treatment that conforms to NICE guidance.
- Trust/PCT audit committees should review implementation plans for NICE guidance in light of this report in order to assess whether they meet the core standards.
- NHS bodies should have a clear implementation plan modelled on the good practice available which links clinical and financial aspects and which is integrated into mainstream financial planning and budgeting.

1

Introduction

Report by the Audit Commission in conjunction with the National Institute for Health and Clinical Excellence (NICE).

This report was prepared by the Audit Commission in conjunction with NICE. It incorporates the findings of:

- an Audit Commission and NICE questionnaire sent to a selection of NHS bodies covered by 10 strategic health authorities (SHAs); and
- site visits undertaken by the Audit Commission and NICE.

In this report, we highlight the financial management challenges that NHS bodies face when implementing NICE guidance, and make practical recommendations for strengthening financial management arrangements to support improved implementation of NICE guidance in the future.

- 1 Guidance issued by NICE primarily in the form of clinical guidelines and technology appraisals plays a vital role in encouraging clinical and cost effectiveness across the NHS.
- 2 To ensure high-quality and equitable provision of care for patients and value for money across the NHS, it is important that NICE guidance is implemented consistently and comprehensively. However, evidence to date suggests that the implementation of NICE guidance by NHS bodies varies. There are a number of reasons for this.
- 3 Implementing NICE guidance presents a financial challenge for NHS bodies, which operate in an environment of competing priorities and limited resources. There is limited information on the financial impact of NICE guidance locally. A high volume of guidance is published and differing funding policies and local arrangements are in place. In such an environment good financial management arrangements play an important role in enabling the implementation of NICE guidance.

- 4 This report, prepared by the Audit Commission in conjunction with NICE, explores the extent to which current financial management arrangements contribute to the implementation of NICE guidance and highlights priority areas for improvement. It aims to raise awareness among NHS bodies of the financial management arrangements that should be in place to underpin the implementation of NICE guidance locally and assist them to improve implementation of NICE guidance through better financial management.
- 5 Using a questionnaire sent to NHS bodies covered by ten SHAs, we examined how NHS organisations currently incorporate NICE guidance into their financial management activities, including how they plan, cost, budget and monitor the financial impact of NICE guidance. In-depth interviews were held at 16 sites to further explore variations in current practice. More detail on the study methodology can be found in Appendix 1.
- 6 The following Chapter of the report provides an overview of NICE guidance, how it is issued and the funding arrangements currently in place. Chapter 3 looks at implementing NICE guidance in the NHS and at the roles and responsibilities of different NHS bodies in implementing NICE guidance. In Chapter 4, we examine financial management in relation to NICE guidance. An analysis of current practice is followed by recommendations on strengthening financial management to better support implementation of NICE guidance. Finally, Chapter 5 summarises key conclusions.

2

Overview of NICE guidance

Background

- 7 The National Institute for Clinical Excellence (NICE) was established as a special health authority in April 1999 to promote clinical excellence and the effective use of resources within the NHS. Although the Institute is part of the NHS, it is an independent organisation that provides national, authoritative, evidence-based guidance on clinical and cost-effective treatments and care for people using the NHS in England and Wales. From 1 April 2005, the Institute's remit was extended to encompass the promotion of good health and the prevention of ill health (public health excellence) and is now known as the National Institute for Health and Clinical Excellence (NICE).
- 8 NICE was created in order to promote the following key healthcare objectives:
 - faster uptake of new technologies;
 - effective use of NHS resources; and
 - equitable access to treatments of proven clinical and cost effectiveness.
- 9 Three types of guidance on clinical excellence are currently produced:
 - **clinical guidelines:** recommendations on the appropriate treatment and care of people with specific diseases and conditions (42 issued to end of August 2005);
 - **technology appraisals:** recommendations on the use of new and existing medicines and treatments (94 issued to end of August 2005); and
 - **interventional procedures:** which covers the safety and efficacy of surgical procedures, not their clinical and cost effectiveness (145 issued to end of August 2005).
- 10 This report focuses on clinical guidelines and technology appraisals only. Guidance on interventional procedures covers the safety and efficacy of interventional procedures and informs safe practice, but there is no imperative for the NHS to use an interventional procedure unless it is recommended as clinically and cost effective by an appraisal or guideline. Consequently, guidance on interventional procedures was not considered relevant when reviewing implementation and the role of financial management. Where the report makes reference to 'guidance', it refers to both clinical guidelines and technology appraisals.

- 11 NICE guidance impacts on the entire spectrum of NHS providers and health professionals – acute trusts (including NHS foundation trusts), mental health trusts, general practitioners and other primary and community care providers. This report focuses on secondary care providers and the commissioning of services by primary care trusts PCTs. However, many of the findings in this report will be of relevance and interest to other NHS bodies.

Clinical guidelines and technology appraisals

- 12 Both clinical guidelines and technology appraisals are based on an evidence-based review of clinical and cost effectiveness. Clinical effectiveness is a measure of how well the medicine or treatment works. Cost effectiveness is a measure of how well the medicine or treatment works in relation to how much it costs – that is, whether it represents good value for money. NICE recognises that something can be both expensive and good value for money.¹
- 13 Topics for consideration can be generated from a number of sources including horizon scanning, policy initiatives and the topic suggestion pages on NICE’s website. Suggested topics are assessed against explicit criteria that include;
- addressing health inequalities,
 - areas where significant variation in clinical practice exists,
 - areas where there is potential to significantly improve a patient or carer’s quality of life; and
 - relationship to NHS priority areas.
- 14 Topics for clinical guideline and technology appraisal development are selected by an advisory committee, which comprises representatives from the Department of Health (DH), Welsh Assembly Government, NHS bodies, healthcare industries and patient/consumer organisations. Recommendations are then made to the Secretary of State for Health, who decides whether to make a formal referral to NICE for development of the guidance.

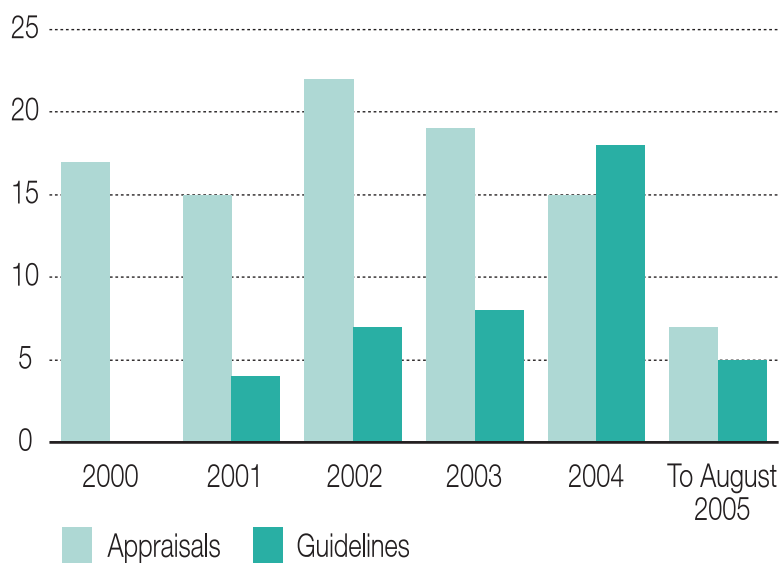
¹ For example, the use of PET scanners in the treatment of lung cancer, which have a unit cost of £971, (approximately £506,000 per annum), but the scanner allows for the detection of secondary tumours, which can reduce the need for costly invasive surgery.

- 15 The NICE website lists forthcoming guidance for the year (including the intended publication date) and also publishes draft guidance that can be used to identify the potential financial impact of its implementation in advance. Final guidance is disseminated by NICE to all relevant healthcare professionals, with a monthly 'Update for Primary Care' sent to general practitioners. The Update focuses on relevant issues for primary care and is accompanied by copies of quick reference guides related to each clinical guideline. In addition, every chief executive and medical director receives a copy of all guidance produced by NICE.
- 16 Upon dissemination of guidance, it is then the responsibility of individual NHS bodies to assess whether the guidance is applicable and, if so, what action is required to implement it.
- 17 While it has always been expected that health professionals will take NICE guidance into account when exercising their clinical judgement, this does not over-ride the responsibility of health professionals to make appropriate decisions according to individual circumstances.

Technology appraisals

- 18 Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England such as:
 - medicines (for example, orlistat for obesity);
 - medical devices (for example, hearing aids or inhalers);
 - diagnostic techniques (for example, liquid-based cytology for cervical screening);
 - surgical procedures (for example, repairing hernias); and
 - health promotion activities (for example, ways of helping people with diabetes manage their condition).
- 19 The annual volume of technology appraisals issued by NICE is illustrated in **Figure 1**.

Figure 1
Annual volume of guidance published by NICE



Source: Audit Commission

- 20** In January 2002, the Secretary of State for Health issued a direction to the NHS about the funding of NICE technology appraisal guidance.¹ The Direction sets out a general principle that NHS bodies must make funding available for treatments recommended by NICE technology appraisals within three months of an appraisal’s publication. This funding direction is to cover all costs associated with implementation, including for example staff, training and capital costs, although this has not been explicitly stated to NHS bodies and, as such, is subject to local interpretation. Many participants in this study cited that the funds they received for implementation were not sufficient to cover all costs associated with implementation. Funds for implementing NICE guidance are included within PCTs’ general allocations from the DH.
- 21** In exceptional circumstances, this three-month rule can be waived, particularly if implementation of the appraisal requires extensive service reorganisation, staff retraining

¹ DH (2002), *Directions to Primary Care Trusts and NHS Trusts in England concerning arrangements for the funding of technology appraisal guidance from NICE*.

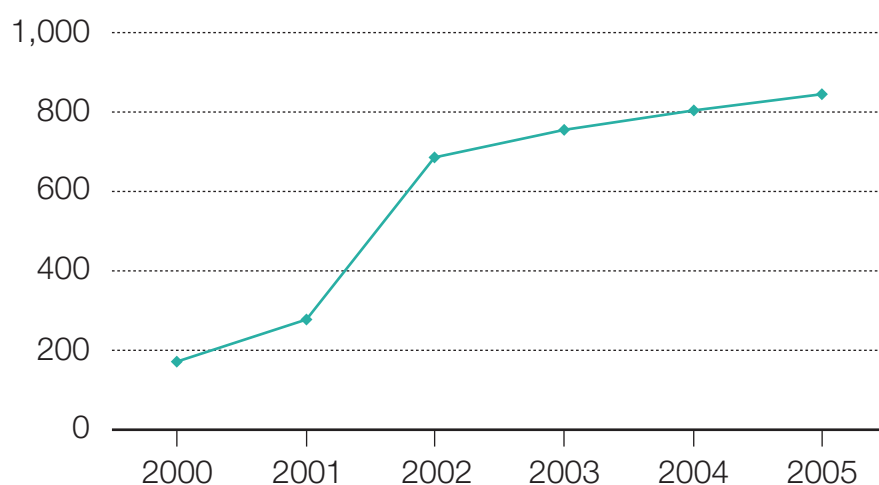
or significant capital investment. For example, the time period for funding of the appraisal on the use of ultrasound locating devices for placing central venous catheters (Appraisal Number 49) was extended to 12 months.

- 22 The direction reflected an increasing emphasis being placed centrally on the consistent implementation of NICE guidance.
- 23 The graph below (**Figure 2**) illustrates the estimated annual cumulative total cost of NICE technology appraisals to the NHS (England and Wales), which has increased steadily since 2002. There was a sharp increase in cost between 2001 and 2002, reflecting the large volume of guidance published in this period. The growth in cumulative total costs now shows some sign of levelling, but technology appraisals still represent a substantial cost to the NHS. However, it should be noted that some technology appraisals are considered to be cost neutral or cost saving. The estimated annual cumulative cost of NICE technology appraisals (£800 million) represents approximately 1 per cent of total NHS expenditure. However, some of these costs would have been incurred without NICE as the NHS adsorbs new technology.

Figure 2

Estimated annual cumulative cost of NICE technology appraisals

Cost to the NHS (£m)



Source: NICE

Clinical guidelines

- 24** Clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England. They are based on the best available evidence.
- 25** Clinical guidelines can change the process of healthcare and improve outcomes. Guidelines that are well constructed and up-to-date:
- provide recommendations for the treatment and care of people by health professionals;
 - can be used to develop standards to assess the clinical practice of health professionals;
 - can be used in the education and training of health professionals; and
 - can help patients to make informed decisions and improve communication between the patient and health professional.
- 26** In contrast with technology appraisals, no direction has been issued to date on the funding and implementation of clinical guidelines. There are good reasons for this. Most notable are the substantial changes to care pathways and services that are often involved in implementing clinical guidelines and therefore the length of time required, which makes issuing a funding direction more difficult.
- 27** Funding to implement clinical guidelines will still need to come from PCT allocations, but, unlike technology appraisals, there is no obligation to provide this. PCTs and providers currently need to agree on timetables, milestones and funding for implementation of all relevant clinical guidelines as part of their service development strategies.
- 28** The only exception has been the recent clinical guideline on fertility, where the DH requires all PCTs to offer women who meet the specified NICE criteria at least one cycle of IVF treatment from April 2005. Consequently, PCTs must ensure that funds are provided to support this recommendation and that treatment is available.
- 29** There is very limited evidence available on the cost to the NHS of implementing clinical guidelines. Cancer service guidance has always included consideration of the costs associated with implementation, but until recently cost assessments were not provided for clinical guidelines.

- 30 From January 2005, costing information will be provided for all clinical guidelines. Costing assessments of three clinical guidelines were undertaken as a pilot in 2004/05 and are currently available for 6 of the 42 clinical guidelines. The estimated costs of these guidelines, for England only, are presented in **Table 1** below.

Table 1
Estimated costs to the NHS (England) of 5 clinical guidelines

Guideline	Recurrent annual cost (£million)	Additional year one cost (£million)
Fertility: assessment and treatment for people with fertility problems	83.9	
Familial breast cancer	2.5	2.1
Depression: management of depression in primary and secondary care	57.7	
Lung cancer: the diagnosis and treatment of lung cancer	23.2	
Violence: the management of disturbed / violent behaviour in in-patient psychiatric setting and emergency departments	10.4	9.6
Post-traumatic stress disorder: The management of PTSD in adults and children in primary and secondary care	26.0	

Source: NICE

- 31 The additional year one costs are one-off costs of implementation, such as training and equipment.

Payment by results

- 32 The introduction of Payment by Results (PbR), the new funding mechanism that will eventually cover the majority of NHS services, will involve further changes to funding arrangements for NICE guidance. Under PbR, hospitals and other acute providers will be paid at nationally set prices (the national tariff) that reflect the complexity of patients, defined according to Healthcare Resource Groups (HRGs).
- 33 From 1 April 2005, PbR is being used to fund elective inpatient activity at all NHS trusts. It will be extended to non-elective inpatient activity, outpatients and accident and emergency contacts from 2006/07. Foundation trusts have a faster implementation timetable and are currently operating under PbR for all these services. By 2008/09, most hospital activity will be paid for under PbR, at the national tariff.
- 34 PbR will present a number of challenges for NHS bodies, as the Audit Commission's report *Introducing Payment by Results; Getting the Balance right for the NHS and Taxpayers* (July 2004) and the forthcoming report *Early Lessons from Payment by Results* both identify. PbR also has implications for the funding of NICE guidance.
- 35 The tariff is set prospectively, but based on a historical cost base. For example, the tariff for 2006/07 will be based on the average cost of providing services (by HRG) in 2004/05 (reference costs). 2004/05 reference costs do not include the costs of a technology appraisal issued in, for example, 2005/06. However, as providers will be expected to comply with that appraisal in 2006/07, the national tariff for that year needs to be adjusted to reflect these costs. NICE has been working with the DH to identify guidance that affects services covered by the tariff, but that are not reflected in reference costs, and to adjust the national tariff structure accordingly.
- 36 Guidance that is not already reflected in clinical practice (and hence in reference costs) will be incorporated into the tariff in two ways:
 - where a recommendation impacts on a specific service or HRG, then a prospective adjustment to the tariff for that HRG may be made. For example, the appraisal on ischaemic heart disease, which recommends the use of drug eluting coronary artery stents applies to one specific HRG (E15: Percutaneous Coronary Intervention). In this case, the tariff for E15 has been adjusted to include the cost difference between drug eluting and bare metal stents and the estimated usage of these stents. A total of

£24 million has been allocated to fund NICE guidance in specific HRGs;^I and

- where additional costs cannot be attributed to specific HRGs (or where cost savings are anticipated) the costs of NICE guidance will be reflected in the overall tariff uplift. For the period 2005/06, this amounts to 0.2 per cent for appraisals and 0.5 per cent for clinical guidelines. The amount included in the general uplift to cover NICE guidance is £327 million.^{II}

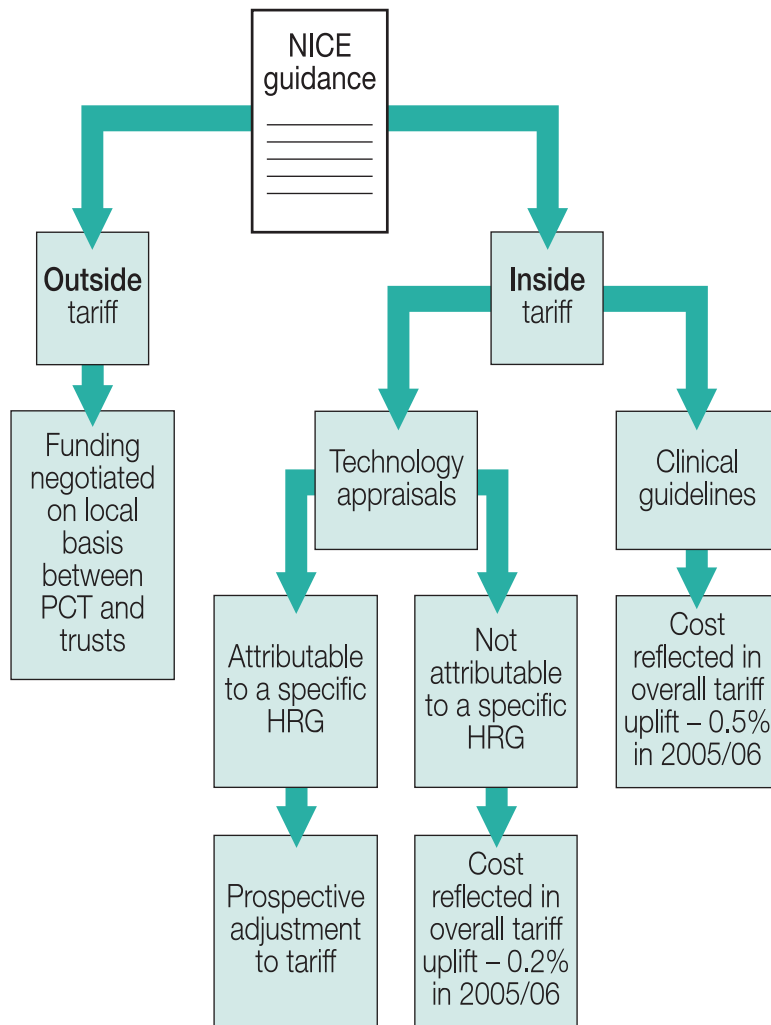
- 37** Figure 3 illustrates the basic principles of how NICE guidance will be included in PbR.
- 38** Further detail on the specific guidance that was incorporated into the 2005/06 tariff can be found in Annex B of the DH Technical Guidance on PbR.
- 39** Certain high-cost drugs, devices and procedures have been excluded from PbR.^{III} The main reasons for these exclusions are that some drugs and devices are disproportionate to the cost of the service (HRG) or there is disproportionate distribution of activity between providers (such as, where treatment is concentrated at particular specialist centres). A good example is Infiximab (used in rheumatoid arthritis), which costs £947 per annum for a typical 70kg patient. The drug is delivered intravenously either at an outpatient attendance or as a day case. Under PbR this would attract a standard payment of either £102 for a follow-up outpatient appointment or £572 for a day case (HRG H26). These amounts do not cover the cost of the drug. Therefore, the costs of the drug Infiximab, are currently excluded from the tariff and funded separately, while delivery of the service will attract payment at the appropriate tariff.
- 40** Primary care and mental health services are excluded from the scope of the national tariff at present. Recommendations that affect these services will still need to be funded separately, on the basis of local negotiations between providers and commissioners.

^I DH personal correspondence with DH PbR team.

^{II} *Implementing Payment by Results: Technical Guidance 2005/06*, July 2005; Annexe A http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4097993&chk+JSLwVc

^{III} A list of tariff exclusions can be found at: <http://www.dh.gov.uk/assetRoot/04/09/79/94/04097994.pdf>

Figure 3
Funding of NICE guidance under payment by results



Source: Audit Commission

- 41 There may be some potential perverse incentives inherent in PbR, which could skew implementation of NICE guidance and could be difficult to manage. An example that one PCT has given relates to the NICE technology appraisal on drugs for rheumatology. There are two options for treatment: one hospital-based (surgery) and the other community-based (Cox II inhibitors). Good practice refers to the surgical option only when pain is unmanageable. Local protocols for referral could be based on relevant NICE guidance and local agreement. However, hospitals have an incentive to increase admissions of patients for surgery outside these parameters in order to increase their income under PbR, even in cases where it would be more cost-effective to treat patients in the community. PCTs should be aware of these incentives and be able to address them through monitoring their local contracts or service level agreements (SLA) with providers.
- 42 Appendix 2 provides a detailed illustration of how NICE guidance should fit into the funding decisions made by PCTs and trusts in the new PbR environment. This diagram implies for simplicity that this is a logical step-by-step process. However, in reality it is a complex process where multiple providers and PCTs interact on an ongoing basis until final agreement is reached.

3

Implementing NICE guidance

- 43 In the previous Chapter, we discussed the nature of NICE guidance and how it is funded. This Chapter considers the respective roles and responsibilities of NHS bodies in implementing NICE guidance, the barriers to effective implementation and the role of financial management in supporting implementation.

Roles and responsibilities

PCTs

- 44 PCTs currently act as both commissioners and providers of NHS services. NICE guidance affects both functions. The role of PCTs as providers is considered in the following Chapter.
- 45 As commissioners, PCTs are responsible for supporting the implementation of NICE guidance via the distribution of funds from their general allocations to providers.¹ This requires them to have in place mechanisms to assess the financial impact of NICE guidance on primary and secondary care and to allocate funds accordingly.
- 46 PCTs vary in their approach to allocating any funds for NICE guidance. The two most frequent approaches we have identified are:
- funding retrospectively passing from PCTs to providers after the treatment has taken place; and
 - providers making an assessment of the likely impact of technology appraisals and clinical guidelines and then requesting funds from PCTs via the local delivery plan (LDP) process.
- 47 Each method carries different risks. In the first case the financial risk remains with the PCT where they agree to provide funding – higher than expected expenditure would need to be absorbed by the PCT. In the second, the risk transfers to the provider, requiring them to manage expenditure within funding provided. As discussed in the previous Chapter, PbR will further change the landscape.

¹ DH (2002), *Directions to Primary Care Trusts and NHS Trusts in England concerning arrangements for the funding of technology appraisal guidance from NICE*.

- 48 The introduction of practice-based commissioning (PBC) will add further complexity to arrangements. GP practices that wish to participate will be given indicative commissioning budgets in order to purchase care on behalf of their patients. PCTS will continue to hold the actual budgets and be responsible for contracts or SLAs with secondary care providers, including monitoring and invoicing functions. However, in making commissioning decisions and in monitoring their own expenditure, GPs will need to be aware of relevant NICE guidance as it applies to both primary and secondary care.

Providers

- 49 The DH's direction on funding technology appraisals applies to trusts as well as PCTS. Trusts must also look to implement clinical guidelines. Providers need to co-operate with PCTs in order to make healthcare interventions available and facilitate compliance with guidance.
- 50 Mechanisms for distributing the funds to the appropriate clinical directorate vary. Two common approaches are:
- placing funds in a central reserve to be released alongside implementation or once guidance has been implemented; and
 - transfer of the funds to clinical budgets to be utilised as and when the guidance is implemented.

SHAs

- 51 SHAs have a broad performance management role for the NHS bodies within their area. We found that individual SHAs interpret their role in relation to implementation of NICE guidance differently. Some consider it an important area, due to the impact on health inequalities and access to healthcare, and are actively involved in monitoring implementation. However, little attention is paid to the financial management implications of NICE guidance by SHAs. Despite this, SHAs are well placed to encourage and facilitate the implementation of NICE guidance and to encourage sound financial management within NHS bodies.

Standards and performance assessment framework

- 52 In 2004, the DH published *Standards for Better Health*, which set out a number of core and developmental standards that healthcare organisations, including NHS foundation trusts and independent providers, are expected to meet. Two standards refer directly to the implementation of technology appraisals and clinical guidelines, recognising their importance in driving local improvements in service quality:

Core Standard (C5): healthcare organisations should ensure that ‘they conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care’.

*Developmental Standard (D2): healthcare organisations should ensure that ‘patients receive effective treatment and care that conform to nationally agreed best practice, particularly as defined in national service frameworks (NSFs), NICE guidance, national plans and agreed national plans on service delivery’.*¹

- 53 NHS bodies are expected to comply with the core standards and are also expected to make progress against the developmental standards.
- 54 *Standards for Better Health* will form an integral part of the new performance assessment of public and private health services in England by the Healthcare Commission – *The Annual Health Check*, which replaces the former star rating system. Under this new system of assessment, providers of healthcare will annually publish a declaration on whether they meet government-set core standards, including those relating to the implementation of NICE guidance.
- 55 With the introduction of these standards and the new performance assessment framework, the priority placed on implementing NICE guidance within NHS bodies is likely to increase, particularly in relation to technology appraisals. At this stage, NHS bodies are only required to ‘take into account’ other guidance issued by NICE, which leaves local organisations greater scope for interpreting the extent of their compliance.

Evidence on implementation

- 56 Research undertaken by the Audit Commission and NICE has identified that to date, the implementation of NICE guidance, particularly clinical guidelines, has not always been timely or comprehensive.
- 57 To date, the implementation rate for technology appraisals has been more consistent than that for clinical guidelines, which in part reflects the funding direction in place for technology appraisals and the relative ease with which appraisals can be implemented compared to the latter. However, the extent to which technology appraisals are being

¹ DH (2005), *Standards for Better Health*.

funded and implemented within the three-month funding direction varies across appraisals and across organisations. From the site visits we undertook, only 25 per cent could verify that appraisals were implemented within three months from publication. Most NHS bodies said that they had aimed to meet the three-month direction, but they could not identify for certain whether this had happened. One trust cited that in one particular case, it had taken them closer to three years to achieve full implementation due to the high capital costs associated with the guidance.

- 58 For the bodies participating in our study, implementation of clinical guidelines by NHS bodies ranged from nil to full compliance with individual guidelines, but it was generally low when compared to technology appraisals. This partly reflects the greater complexity associated with implementing guidelines, which often require a longer implementation period and span primary and secondary care settings. In addition, the absence of any specific funding requirements means that they are competing with other priorities for funds.

Barriers to implementation

- 59 An extensive body of literature already identifies the various barriers to implementing clinical guidelines in general.^{I, II} There is also some more specific work on the implementation of NICE guidance.^{III}
- 60 Earlier research has demonstrated that implementation is more likely where there is strong professional support, a sound evidence base and no increased or unfunded costs. Findings from this study were consistent with this. We found that clinical guidelines in particular tended to be implemented more regularly where an enthusiastic champion (usually a clinician) develops a business case as part of the LDP to obtain the appropriate funds. Furthermore, organisations that have established systems for tracking implementation and where the professionals involved are not isolated have a better track record with implementation.

I Foy, R Walker, A & Penney G (2001), Barriers to Clinical Guidelines: The need for Concerted Action, *Clinical Governance* 6 (3) p166-174.

II Grol, R (1997), Beliefs and Evidence in Changing Clinical Practice. *BMJ* 315 p418-21.

III Sheldon, T A et al (2004), What's the Evidence that NICE Guidance has been implemented?, results from a national evaluation using time series analysis, audit of patients' notes and interviews, *BMJ* 329.

- 61 Previous studies have found that clinician resistance is one of the biggest barriers to implementation. As part of this study, we revisited perceptions of the barriers to the implementation of NICE guidance and, given the costs associated with NICE guidance, we explored the extent to which financial management arrangements are a barrier.
- 62 We found that the biggest **perceived** barrier to implementation among NHS bodies, for both clinical guidelines and technology appraisals, was lack of money (**Figure 4**).

Figure 4

Perceived barriers to implementing clinical guidelines and appraisals

- Lack of money
- Lack of access to necessary resources – staff, equipment or space
- Too much change already occurring
- Too busy
- Resistance to change
- Apathy – lack of interest in implementing guidance
- Lack of knowledge – staff do not know that the guidance exists

Source: Audit Commission

- 63 We found that 85 per cent of respondents identified that the funds available to implement technology appraisals were insufficient, particularly in relation to high-cost appraisals, such as Drotrecognin for sepsis (Appraisal number 84) and etanercept and infliximab for rheumatoid arthritis (Appraisal number 36). A number of respondents (33 per cent) identified that NICE had issued guidance in 2002/03 that they were unable to fund, which included Anti TNF, photodynamic therapy (despite the three-month funding direction being waived for nine months) and coronary artery stents. In individual cases this was attributable to the high costs of implementation and lack of local funding available. For example, one respondent cited that additional staff training and new equipment was needed before the appraisal could be implemented in full.
- 64 The differences in our findings on the barriers to implementation and the findings of earlier work partly reflect the different research and approaches. However, they are not necessarily inconsistent. This study identified that where robust implementation systems are in place, funding was not the biggest barrier to implementation (clinical resistance tended to be more significant). This suggests that where NHS bodies have a robust system in place for implementing NICE guidance, factors other than lack of funding are of greater concern.

- 65 We found that one of the most prevalent difficulties is that the total cost of implementing guidance is not known when financial plans are produced and budgets are set at a local level. We identified two factors behind this: a lack of knowledge about the existence of guidance (current and forthcoming) when planning and budgeting and uncertainty surrounding the costs of implementation. The perception that lack of money is a barrier may be misplaced if the organisation has limited awareness of the actual costs associated with NICE guidance. This indicates that good financial management arrangements are a key component of a strong implementation system.
- 66 This finding is supported by a key report by Professor Mike Richards^I published in 2004, which found variations in the use of cancer drugs across the country. This resulted in a letter from Lord Warner to chief executives of NHS bodies outlining the DH's plans to ensure improved implementation of NICE guidance across the NHS on the basis of the report's findings.^{II} As well as measures to improve the availability of information to help monitor implementation of guidance (for example, improved information on prescribing patterns) and ongoing reviews of dissemination and communication around guidance and good practice, the plans included ensuring that NICE guidance provided advice on all the significant costs of its guidance and the best ways of ensuring full implementation.
- 67 Different interpretations of the funding direction on technology appraisals have in places led to a perception that funding provided for implementation is not sufficient (at least, at the local level). Funding received by providers to implement technology appraisals often only covers the cost of the actual drug and not the associated costs of implementation, such as the additional staff and equipment (the second biggest barrier to implementation).
- 68 Overall, funding and competing priorities for these funds may be factors in determining implementation. However, there are clear weaknesses in the current financial management arrangements underpinning the implementation of NICE guidance (notably costing). Addressing these weaknesses will improve implementation of NICE guidance locally. The following Chapter explores how local arrangements can be strengthened.

I DH (2004), *Variations in usage of Cancer Drugs Approved by NICE*.

II DH (2004), <http://www.dh.gov.uk/assetRoot/0/4/08/39/04083913.pdf>

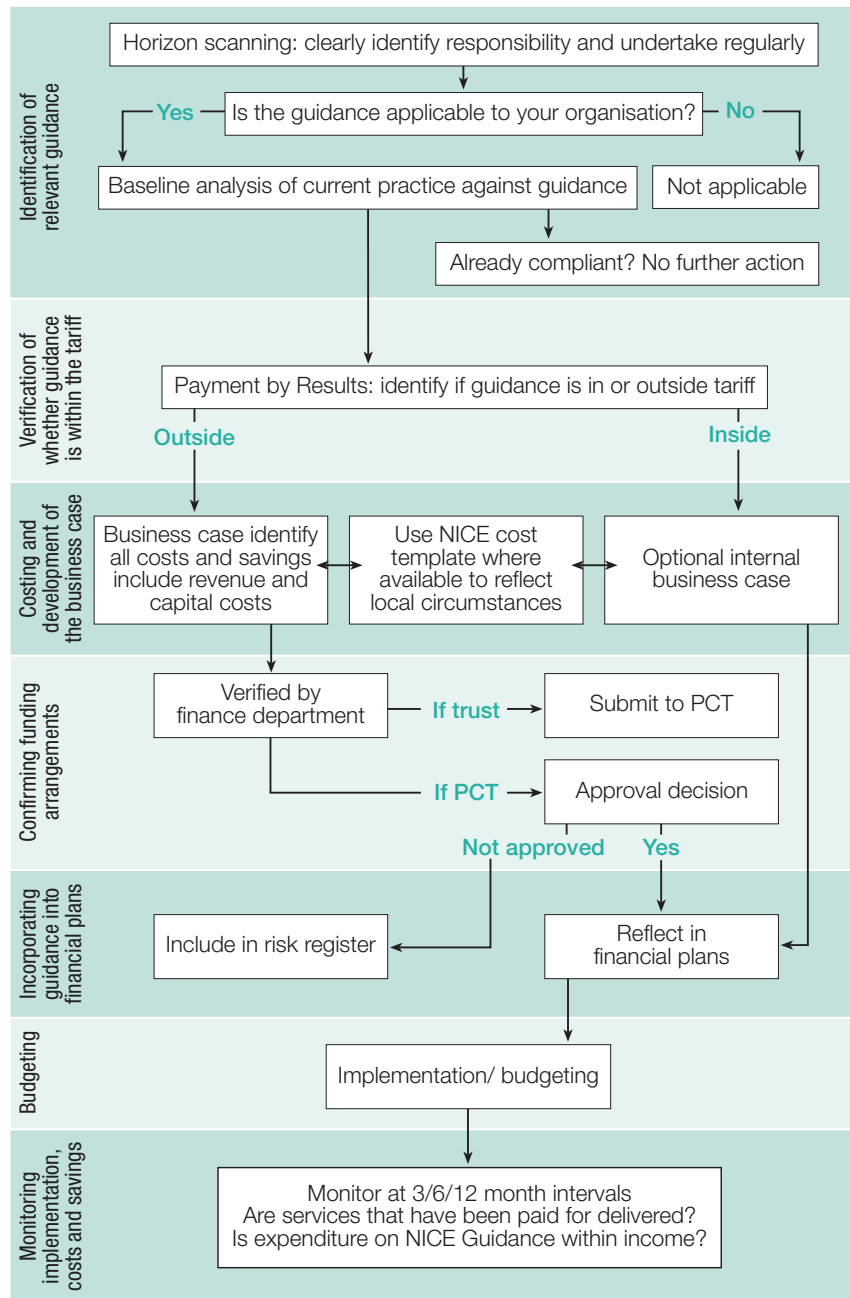
4

Strengthening financial management to support the implementation of NICE guidance

- 69 Good financial management arrangements are vital if NHS bodies are to meet their objectives and deliver effective healthcare to patients. As highlighted in the Commission's report *Achieving first-class financial management in the NHS*, 'organisations that have good financial management processes will be better able to redesign and improve services'.¹
- 70 In the previous Chapter, we considered the extent to which financial management arrangements and funding constituted a barrier to implementation of NICE guidance. We found that good financial management has an important role to play in improving implementation rates. This Chapter considers the different stages of implementing NICE guidance and the relevant financial management activities that should be in place in each stage.
- 71 **Figure 5**, overleaf, sets out the financial management processes that NHS bodies should follow when implementing NICE guidance. An illustrative timeline (**Figure 6, overleaf**) outlines the financial activities that need to be undertaken throughout the year. The actual timing of activities will vary according to local circumstances.

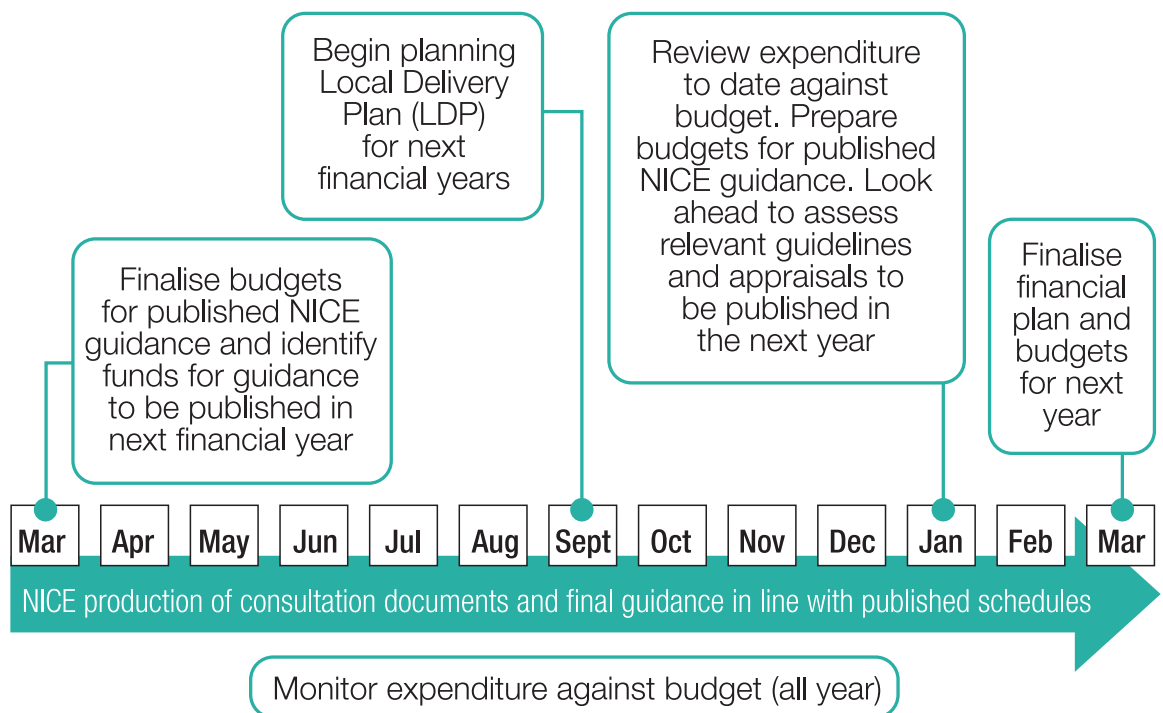
¹ Audit Commission (2004), *Achieving First-class Financial Management in the NHS*.

Figure 5
Implementing NICE guidance – recommended good financial management model



Source: Audit Commission

Figure 6
Timeline of financial activities for implementation of NICE guidance



Source: Audit Commission

72 We now consider each stage of the financial management model in more detail.

Identification of relevant guidance

- 73 As discussed in Chapter 2, NICE publishes guidance throughout the year, including the release of draft guidance and the intended publication date. Final guidance is disseminated widely – to all relevant health professionals and to every chief executive and medical director.
- 74 NHS bodies should have in place a systematic process to horizon-scan for future and current NICE guidance in order to respond appropriately to the release of guidance, assess its relevance, whether or not they are already compliant and consider the potential financial impact of its implementation. An individual NHS body may already be partially or

indeed fully compliant with the guidance and this will have a significant impact on how much it will cost to implement.

- 75 Some 79 per cent of the NHS bodies that participated in this study indicated that they were aware of the guidance that NICE intended to issue, but that little or no action was undertaken to assess its financial implications prior to publication. This indicates there is considerable room for improvement in the way that forthcoming NICE guidance is translated into a more proactive assessment of likely financial impact within NHS bodies prior to guidance publication.
- 76 Collaboration between providers and commissioners, and across clinical teams, is an important success factor for effective horizon scanning (**Case study 1**).

Case study 1

PCTs and providers in Bristol, North Somerset and South Gloucestershire work collaboratively across primary and secondary care to identify the impact of appraisals and forecast the level of expenditure required across the health community. This requires effective communication and active engagement between all parties, and leads to highly effective, financially sound implementation. Using this collaborative approach, the majority of NICE guidance has been successfully implemented within this health community.

Source: Audit Commission

- 77 Respondents indicated that the lack of knowledge about forthcoming NICE guidance was sometimes due to horizon scanning being a time consuming process. This is particularly the case where there are no dedicated staff responsible for the implementation of NICE guidance. The majority of respondents identified that responsibility for implementation of NICE guidance had been allocated to one individual, but only formed a small part of that individual's responsibilities and very little time was available to perform the tasks required.

Recommendations

All NHS bodies should:

- Ensure continuous horizon scanning for forthcoming NICE guidance throughout the year.
- Devote sufficient resources to supporting this activity and ensure that the findings are acted upon.
- Consider sharing the responsibility for horizon scanning and assessing the potential implications of NICE guidance. This could work particularly well in PCT clusters or even on a SHA-wide basis.
- Undertake a thorough assessment of current clinical activity to determine whether they are already compliant with the guidance and, if not, identify the practices that need to change.
- Assess the financial impact of NICE guidance while it is in draft form and factor this into local planning.

Verification of whether guidance is within the tariff

- 78** As discussed in Chapter 2 of the report, PbR changes the way the majority of NICE guidance is currently funded. The system already applies to some services provided in acute trusts and by 2008/09 it is expected to cover most hospital activity. NHS bodies need to familiarise themselves with the processes and implications of PbR and how it will impact on the implementation of NICE guidance.
- 79** As previously discussed, funding for a number of technology appraisals and some clinical guidelines will be covered in the tariff under PbR and will no longer require separate funding. However, this does not apply to all guidance – there are exceptions that will still be subject to local negotiation to agree funding.
- 80** It is vital that NHS bodies are aware which guidance is inside the tariff and which is outside it. We found that many NHS bodies are still getting to grips with PbR, and many are unsure about how it will affect the funding and implementation of NICE guidance at the local level.

- 81 Locally, there should be a common understanding between commissioners and providers about which guidance is already funded through PbR and which will require separate funding. Where NICE guidance falls outside the tariff, separate funding will still need to be negotiated. Where the costs of NICE guidance are included in the tariff, providers will no longer receive specific funding for the implementation of some technology appraisals and guidelines, although there will be cases where local negotiation may still be required. Providers will therefore need to manage expenditure on implementing NICE guidance within their total income.
- 82 NICE could also assist NHS bodies by indicating at draft stage whether guidance is likely to be inside or outside the tariff which will help with financial planning for the implementation of guidance.

Recommendations

NHS bodies should:

- develop a clear understanding of which NICE guidance is included within the tariff under PbR and which requires separate funding. There should be a clear and consistent understanding of this between the parties involved.

NICE should:

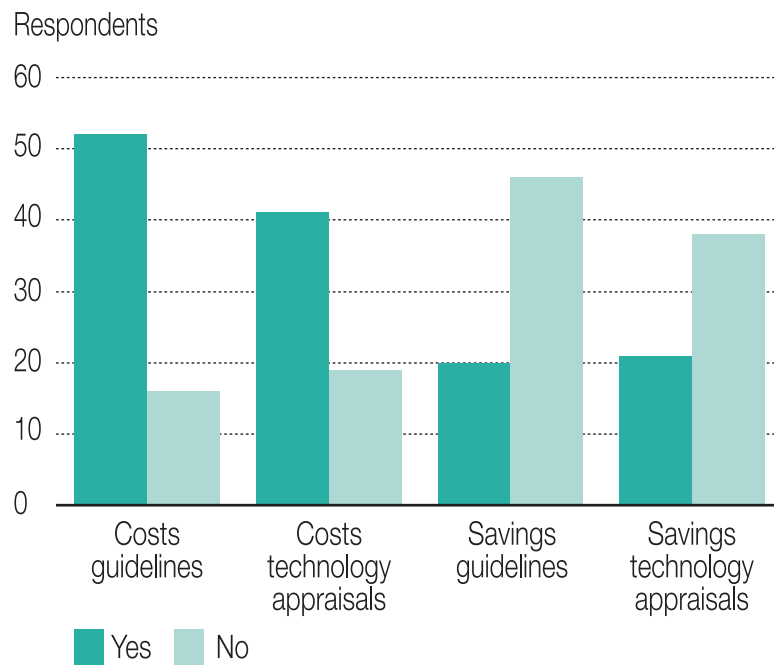
- in conjunction with the DH PbR team, indicate at draft stage if guidance is likely to be inside or outside of the tariff.

Costing and development of the business case

- 83 Once the organisation has determined that action is required to implement the guidance and whether it is included within the tariff, the costs of implementation (or possibly savings) will have to be identified.
- 84 As we identified in Chapter 3, accurately estimating the financial impact of NICE guidance is complex. It presents a barrier to accurate planning and therefore to successful implementation. Many respondents did not identify costs or savings associated with guidance, which makes accurate financial planning very difficult (**Figure 7**).

85 Producing a business case for each piece of NICE guidance is one approach that formalises the costing process and supports effective implementation (although the suitability of this will largely depend on the organisation’s internal processes and the anticipated level of investment required). This is particularly important in cases where guidance is not incorporated into the tariff. Business cases should contain a comprehensive assessment of all the additional costs incurred in implementing the guidance, covering both capital and revenue items. The business case should also make a distinction between the costs in year one and subsequent years, if additional start-up costs will be incurred. The business case should include a clear agreement about what needs to happen and who will be responsible. An example of a pro-forma business case, used by Cambridge University Hospitals NHS Foundation Trust, can be found in Appendix 3.

Figure 7
Identification of costs and savings in relation to NICE guidance



Source: Audit Commission

86 Another key finding of this study is that NHS bodies would find the provision of costing information the most useful tool when planning for implementation of NICE guidance (**Figure 8, overleaf**).

- 87 Some tools to support costing of technology appraisals are already widely available. For example, tools provided by the Prescribing Support Unit or UK Medicines Information (UKMI) can assist in forecasting the financial impact for the local health care community. These tools are based on assumptions and allow NHS bodies to estimate the cost of introducing national guidance and estimated impact on clinical practice and prescribing budgets. However, to date, the available costing information has generally been limited.

Figure 8

Most useful tools for planning implementation:

Clinical guidelines

1. Costing information.
2. Clinical guidelines tailored to your type of organisation.
4. Examples of best practice.
5. Clinical audit advice.
6. More accurate timelines for the publication of guidelines.

Technology appraisals

1. Costing information.
2. Technology appraisals tailored to your type of organisation.
3. Clinical audit advice.
4. Examples of best practice.
5. More notice.

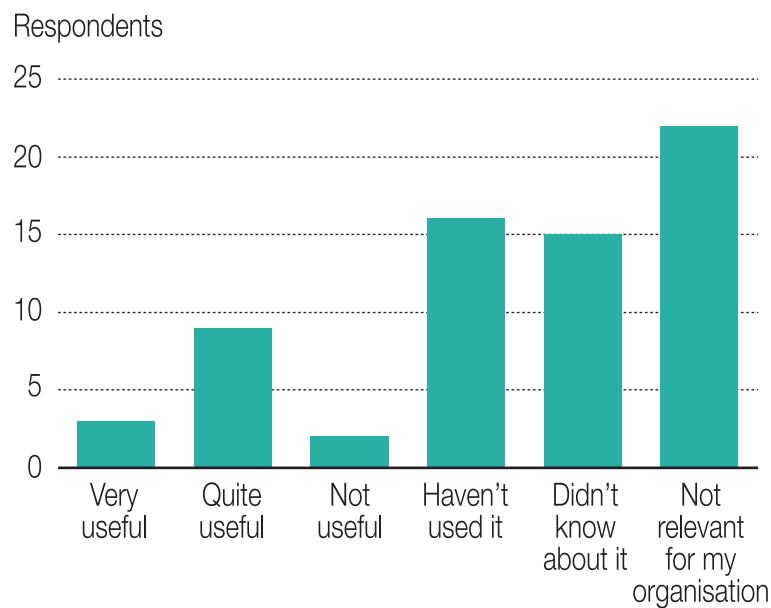
Source: Audit Commission

Cost templates

- 88 It is in recognition of the difficulties that local bodies face in estimating the financial impact of NICE guidance that NICE has developed cost templates to accompany their guidance, which we discussed in Chapter 2. While there are currently only six cost templates available, from January 2005 all new clinical guidelines, and from Autumn 2005 all technology appraisals, will have a cost template, unless it is determined that there is no significant cost impact for a specific piece of guidance. All existing guidance will have a cost template if it is amended when reviewed, usually three-four years after its initial publication.

- 89 Cost templates enable PCTs, NHS trusts and NHS foundation trusts to estimate the cost of guidance and replace general assumptions on treatment and cost variables with ones that depict their current local position.
- 90 The cost information presented within the templates can help to inform local action plans and then be used in the development of business cases and reflected in the NHS body's financial plans.
- 91 Using the templates requires NHS bodies to consider how the guideline will be implemented, whether it can be done through redirecting existing resources, or whether additional resources will be required. Local costing expertise is required to do this and to estimate costs not covered by the template. This requires relevant skilled personnel, for example, an experienced finance professional working closely with the relevant clinical lead.
- 92 We explored current awareness in the NHS of the cost template for fertility – issued in February 2004 – and the extent to which it was being used by NHS bodies. A sizeable proportion of organisations (22 per cent) were unaware of the existence of the cost templates, indicating that some work needs to be undertaken by NICE to raise awareness among NHS bodies.
- 93 We found that while only a small percentage of respondents (20 per cent) had used the template, it was considered a useful tool (**Figure 9, overleaf**). As the fertility cost template is designed for use at PCT level, a number of organisations (22) correctly identified that the cost template was not relevant for them.
- 94 Some of the comments received on the costing template included:
- 'Useful tool, but would be useful to score and calculate the impact of social indicators.'
 - 'Template used across the SHA at the Priorities Forum, used template to produce costing.'

Figure 9
Use of NICE fertility cost template



Source: Audit Commission

- 95** A small number of NHS bodies outlined the existence of their own in-house system of costing NICE guidance. Such systems had been developed in the absence of centrally provided guidance. However, some were very superficial in their approach. For example, one did not assess capital costs and only identified costs at a very basic level, such as the extra staff required but without specifying the grade of staff required, which would have obvious financial implications. On the whole, costing was more common when planning for technology appraisals rather than clinical guidelines.
- 96** Greater use of costing templates by NHS bodies could help to improve implementation of NICE guidelines. We identified a direct correlation between the identification of costs and savings and the formalisation of the implementation arrangements. Those bodies that have established implementation policies tended to assess resource implications in relation to costs and savings of NICE guidance more systematically as part of their implementation policy. Identifying the potential financial impact as early as possible and the subsequent planning associated with this enables better resource management and more effective implementation. NHS bodies must either develop their own costing systems that accurately assess the costs (covering both capital and revenue) or use the costing model developed by NICE and adapt it to suit local circumstances.

Recommendations for improving costing

- NICE should take steps to ensure that NHS bodies and, in particular, finance and commissioning professionals are aware of the cost template, how it should be used and the benefits of using it.
- NHS bodies should use the cost templates developed by NICE where appropriate and adapt them to reflect local circumstances.
- NICE should set out clearly the assumptions made in the model, which will make it easier for NHS bodies to adapt to reflect local circumstances.
- NHS bodies should ensure that they have the costing expertise locally to apply the costing template provided by NICE and that the finance team have engaged clinicians in the process.
- NHS bodies should use a business-planning template – like the one included in appendix 3 – to formalise arrangements and secure approval where there are significant resource implications.
- NHS bodies should use financial tools, such as those provided by UKMI and the Prescribing Support Unit, to estimate costs.

Confirming funding arrangements

- 97** Where NICE guidance is not covered by the tariff, once it has been costed and the business case developed, NHS bodies will have to identify how it will be funded. As set out in Chapter two, PCTs are expected to meet the cost of treatments recommended by NICE out of their general annual allocations. There are no specific ‘ringfenced’ or ‘earmarked funds’ for the implementation of NICE guidance. Although funds for the future costs of NICE guidance is included in PCT allocations, the availability of these funds for implementation still needs to be negotiated locally and take into account affordability locally, as well as service development priorities.
- 98** Poor relationships between providers and commissioners locally make it more difficult to negotiate funding to implement technology appraisals and or clinical guidelines. Conversely, strong relationships between NHS bodies will assist with sound implementation, for example, through easier negotiations on funding, joint action planning and adequate assessment of financial impact.

Recommendations

- PCTs and trusts should work together to identify local priorities for funding of NICE guidance that is outside the tariff and discuss appropriate funding. Strengthening local partnerships around NICE guidance through the use of clinical networks will help to improve implementation.

Incorporating guidance into financial plans

- 99** NHS bodies must have robust arrangements for planning their finances if they are to deliver services and meet their organisational objectives. For financial planning to be effective it must be integrated with service planning and be based on horizon scanning (to identify likely demands that will be placed on resources and the level of resources that will be received) and the accurate costing of existing services and service developments. Successful implementation of NICE guidance requires that the horizon scanning, impact assessment and costing activities discussed previously all feed into the financial planning process. The overall financial plan should also include an assessment of the likely financial risks stemming from NICE guidance, their likely impact and how they can be mitigated.
- 100** In our study, only 26 per cent of participating NHS bodies indicated that they always assessed the financial implications of draft NICE guidance as part of their financial planning process. We have already discussed that while a significant proportion of organisations are aware of NICE guidance, it appears that, in many cases, this awareness is not being translated into meaningful action at an operational or financial level.
- 101** The development of an action plan is crucial to ensuring implementation of guidance and should inform the overall financial plan. Our study found that only 24 per cent and 12 per cent of NHS bodies always produced an action plan for clinical guidelines and technology appraisals respectively.
- 102** Only 15 per cent of organisations always reflect these action plans in their financial plans. This is due to a number of factors, including lack of time to consider the likely financial impact, insufficient skills to carry out the financial assessment and a lack of interest in that particular guidance.

Recommendations to improve financial planning

- Draft guidance should be assessed for financial impact, accurately costed and fed into the financial planning process.

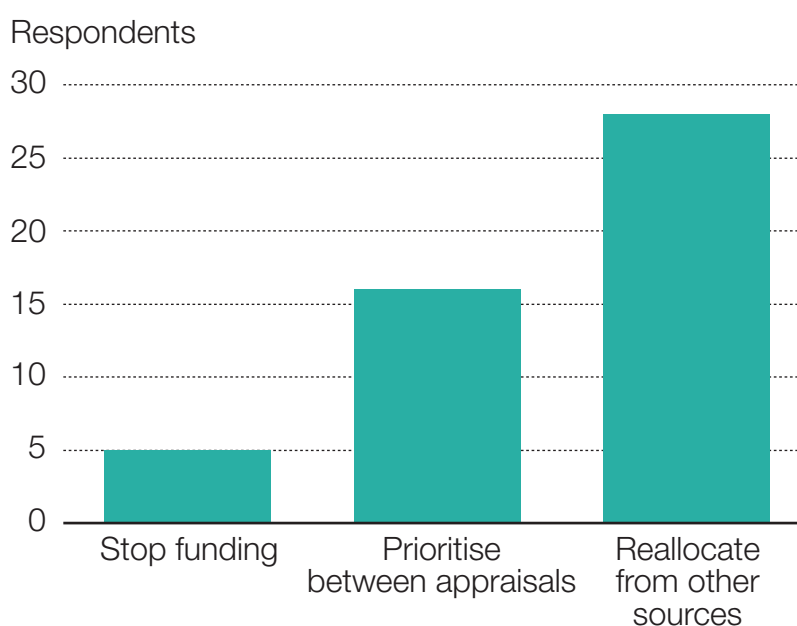
- Action plans should be systematically reflected in financial plans so that the organisation can ensure that it has sufficient funds to carry out the planned activities. Both the plans should be updated regularly to take account of new developments (for example, if new guidance is issued).
- The financial plan should include an assessment of the likely financial risks stemming from NICE guidance, their likely impact and how they can be mitigated.

Budget setting

- 103** Once it has been agreed that a piece of NICE guidance should be implemented and funding has been secured (either via the tariff under PbR, local agreement from PCTs as part of the LDP process or from existing internal sources), provision should be made in the financial plan and then in the annual budget.
- 104** The majority of respondents (65 per cent) have budgeted for the implementation of one or more clinical guidelines in the last three years. However, this means that 35 per cent did not budget for a single guideline in the last three years.
- 105** Budgeting arrangements will vary according to whether the guidance has been incorporated into the national tariff and depending on how commissioners choose to allocate funding to providers. In Chapter three, we discussed different funding distribution mechanisms used by commissioners, as well as the different approaches to budgeting used by providers.
- 106** We found that the two most common methods among those NHS bodies that did budget for NICE guidance was either to hold the funds centrally in a ‘NICE reserve’ or to devolve the funds to the budgets of the services affected. Holding the funds centrally can make it difficult to monitor expenditure against expected levels and can lead to NICE guidance being seen as something separate from the usual clinical activity (whereas devolving budgets is more likely to fully engage clinicians). Incidentally, it can also lead to difficulties when reference costs are prepared as central reserves are usually apportioned over all activities, when clearly the costs should only be reflected in some specific activities. Conversely, holding the funds centrally may mean that the organisation has tighter control over how the resources are being used and may help to ensure that they are used exclusively for NICE implementation.
- 107** During our research, we found examples of organisations diverting funds from the implementation of NICE guidance to meet other priorities (for example, to contribute to the overall achievement of financial balance and implementation of the consultants’ contract).

108 We reviewed the actions that NHS bodies take when they identify that funds are insufficient to support the implementation of technology appraisals. As shown in **Figure 10**, below, we found that the majority of respondents reallocate funds from other areas in order to fund technology appraisals. However, some organisations do cease funding when the budget is exhausted or prioritise between appraisals.

Figure 10
Action taken upon insufficient funds to implement technology appraisals



Source: Audit Commission

Recommendations

- NHS bodies should routinely incorporate NICE guidance into their budgeting processes.
- If a reserve/central budget is established for NICE guidance, when the guidance is implemented there should be a virement to the budgets of individual services, so that implementation of the guidance is mainstreamed into clinical practices and can be monitored accordingly.

- Budgets should be constructed so that the costs of NICE guidance can initially be separately identified and monitored.
- Where a guideline is implemented part way through the year, as with other service developments, provision should be made for increased costs and the full-year effect of the guideline should be budgeted for in subsequent years.
- Where savings are anticipated service budgets should be reduced accordingly and expenditure against the budget monitored to ensure that the expected savings are being achieved.

Monitoring implementation, costs and savings

- 109** Monitoring the implementation of NICE guidance, and the associated expenditure, is important on two levels.
- 110** Firstly, NHS bodies should monitor whether guidance is actually being implemented. With the increasing emphasis on implementation of NICE guidance, particularly the new performance assessment framework and the introduction of PbR, the risk to individual organisations of non-compliance with guidance has increased.
- 111** NHS bodies will be required to make an annual declaration that they have met agreed standards as part of the Healthcare Commission's performance assessment. Boards should be concerned with establishing stronger systems to provide them with assurance on the implementation of NICE guidance.
- 112** It may be the case that some organisations decide – for a variety of reasons – not to implement a specific piece of NICE guidance. Where NICE guidance cannot be implemented, particularly technology appraisals, an exception report should be logged, highlighting non-compliance. Non-implementation of NICE guidance should be identified on a risk register used jointly by PCTs and trusts and a plan for implementation and monitoring of the risks associated with non-implementation should be developed.
- 113** In addition, where the costs of adhering to NICE guidance are covered by the tariff, PCTs will be paying providers for the provision of clinical care to their patients that reflects that guidance. PCTs should ensure that where costs of NICE guidance are covered through the tariff, providers are delivering the service and quality of care being paid for.

- 114** Secondly, NHS bodies should monitor the cost of implementing NICE guidance. While both the Commission and NICE recognise that it is difficult to monitor expenditure particularly in relation to clinical guidelines, it is essential that, where possible, expenditure is tracked and compared against the estimated costs and savings identified within the business case. If costs exceed what was expected, this should be recognised and action should be taken to bring expenditure back into line or additional funds should be identified. Monitoring of actual expenditure against what was planned will also help to refine costing approaches and inform the subsequent year's financial planning process.
- 115** How easy it is to monitor expenditure will depend to a large extent on the budgetary arrangements that have been put in place and the information that is available to support it. Most NHS bodies involved in the study (58 per cent) do not currently monitor expenditure on clinical guidelines and those that do, do so sporadically. While clinical guidelines have long implementation periods and may often require a change to care pathways or service redesign, it is important that monitoring of expenditure takes place during the implementation period.
- 116** A number of respondents (46 per cent) reported that they monitored expenditure on technology appraisals. In some cases this was because technology appraisals normally relate to drugs and such expenditure is already monitored by pharmacy staff, with no additional processes or information necessary. However, there are a number of complexities. A common concern raised during the study, was how organisations can control prescribing and thus expenditure if a drug is on a hospital formulary only to be prescribed in the conditions recommended by NICE. One action that could be taken is to introduce clear prescribing protocols within the organisation and assess compliance with the protocols so that drugs are only prescribed for conditions recommended by NICE.
- 117** One of the biggest challenges in monitoring implementation and expenditure relates to the limitations of the information technology (IT) infrastructure. The IT systems at some NHS trusts are not sophisticated enough to identify whether a patient with a particular condition has received the appropriate drug recommended in a technology appraisal. Consequently, it is difficult to identify those patients who have not received a drug or treatment in accordance with the protocol, although monitoring may be possible for specific high-cost, low-volume items.

Recommendations

- Where guidance is not being implemented, an exception report should be produced and included in the organisation's risk register to be considered by an appropriate committee.
- Boards should review the arrangements they have in place to provide assurance on the implementation of NICE guidance, to inform their self-assessment on compliance with standards under the Annual Health Check.
- All bodies should have in place arrangements to monitor expenditure on NICE guidance on a regular basis. Particular attention should be paid in the initial years of implementing the guidance.
- Any savings anticipated should be closely monitored and reported to ensure that they are delivered.
- As with any other types of expenditure, where expenditure on NICE guidance varies from what is expected, action should be taken to bring expenditure within budget or to source additional funds.
- Where higher costs are incurred as a result of NICE guidance being implemented inappropriately (for example, drugs being prescribed for conditions not recommended by NICE as considered above) this should result in clinical implementation plans being amended.
- Where the costs of implementation are significantly different from those identified in the business case, the costing model should be reviewed and lessons learnt when subsequent guidance is costed.

Integrating financial management activities into the implementation process

- 118** While this report focuses on good financial management, these arrangements need to be integrated within robust overall implementation processes.
- 119** A recurring theme throughout this report has been the importance of multidisciplinary teams in implementing NICE guidance. Our research indicates that implementation of clinical guidelines is (and should be) primarily driven by a clinical lead with an interest in the area. However, the enthusiasm of a single clinical lead is not sufficient on its own to implement NICE guidance. Those organisations that successfully implement NICE

guidance on a consistent basis have a member of the finance team actively involved in the implementation process, alongside active clinical engagement. Successful implementation will be facilitated by managerial and clinical leaders working together with active support from finance professionals, under the leadership of a clinical champion.

- 120 To assist NHS bodies with implementation, NICE's implementation systems directorate has developed a 'how to' guide using a step-by-step approach. This guide is due to be launched at the NICE conference in December 2005.
- 121 The content of this guide has been informed by effective implementation processes that are known to be operating across the country and builds on the foundations provided by the National Prescribing Centre in *Implementing NICE Guidance: A practical handbook for professionals* (2001).
- 122 There are already examples of good practice in this area, demonstrating effective implementation and sound implementation planning into which robust financial management processes can be incorporated.
- 123 A notable example is the approach taken by Mid Staffordshire General Hospital NHS Trust, which won the Health Service Journal award for implementation of NICE guidance (**Case study 2**).

Case study 2

Mid Staffordshire General Hospital NHS Trust

Mid Staffordshire is a medium-sized busy hospital where implementation of NICE guidance has been identified as a priority.

The Trust Board of Mid Staffordshire General Hospitals NHS Trust made the implementation of NICE guidance a 'must do' priority and a full-time team is in place specifically tasked with translating guidance into local practice and ensuring that effective audit and monitoring arrangements are in place.

The strategy for NICE guidance implementation in Mid Staffordshire encourages clinical leaders to contribute to guidance development at the draft stage. Upon publication of the guidance, robust methods of receipt, dissemination, implementation and audit/monitoring arrangements have been applied.

Mid Staffordshire has identified the following key objectives with respect to NICE guidance:

1. Make the Trust aware of all NICE guidance and related topics.
2. Provide best practice to patients as per standards specified by NICE guidance.
3. Establishment of NICE Implementation Group, which considers financial implications of guidance.
4. Effectively disseminate guidance to clinicians.
5. Coordinated approach to produce timely response from clinical leads for relevance, implementation and monitoring.
6. Identify and act upon areas of non-compliance.
7. Initiate audit/monitoring arrangements of all relevant guidance.
8. Record adherence to guidance.
9. Make the whole process transparent.

The process begins with horizon scanning guidance when it is still in draft format. A business case, including financial implications, is produced and presented to the Local Strategic Priorities Forum.

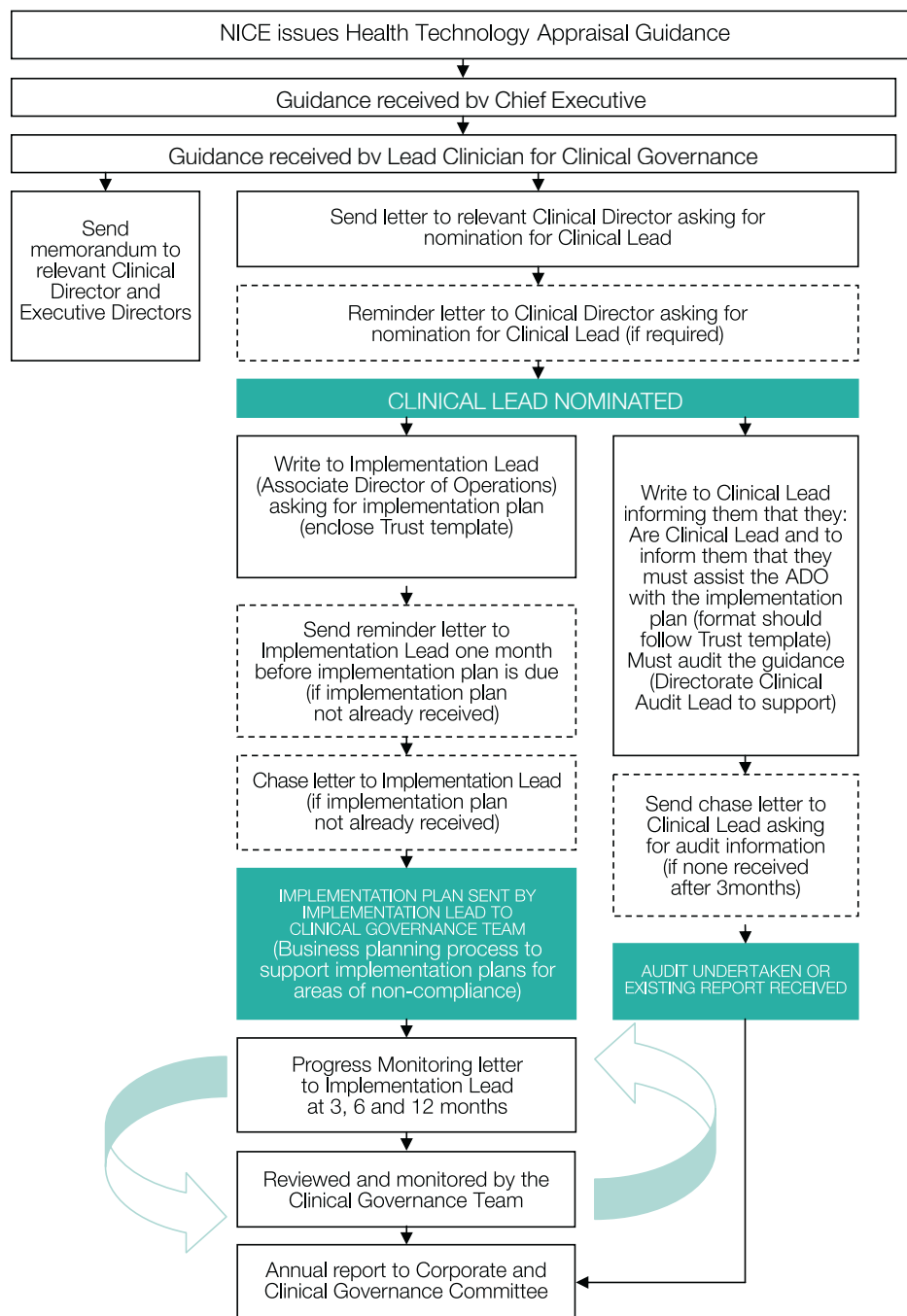
Each piece of guidance is subject to the completion of a questionnaire, which includes sections on; current practice, dissemination, infrastructure, role re-design, cost impact, training/education and monitoring. In this way the Trust can ascertain compatibility with current practice. Cost impact is identified across three areas: technology/drugs, infrastructure/staff and monitoring. Timescales for implementation are also identified, which in turn impact on costs.

Questionnaires are issued to identified clinical leads within one week of guidance being published, with a two-week deadline for completion and return. An exception reporting process has been developed when compliance cannot be achieved and consequently these areas are flagged on a risk register. Where there is an exception report is logged, the reason has to be identified.

Source: Mid Staffordshire General Hospital NHS Trust

- 124 Another example of good practice can be found at Cambridge University Hospitals NHS Foundation Trust. Their high success rate in implementing clinical guidelines is attributable to the fact that they are handled in the same manner as NSFs and other guidance. This means that all guidance is subject to the same rigorous appraisal process of business cases (**Figure 11**). NICE guidance is not singled out as something that is optional but rather an integral part of planning and prioritisation, thereby creating a culture in which the assessment and implementation of guidance is given weight.
- 125 In addition, clinical networks can be utilised to implement NICE guidance. A number of NHS bodies highlighted the existence of clinical networks for clinical areas such as cancer, where guidance and practice are actively discussed in a multi-disciplinary working group. Within these groups the rigorous implementation procedures that are applied to NSFs are discussed and the same process is applied to NICE guidance, particularly clinical guidelines. One respondent identified that as many as 25 clinical networks existed within their SHA. They provide a useful forum to facilitate the appraisal and implementation of guidance without requiring additional resources. While the numbers of networks vary across the country, groups are known to exist in each SHA.

Figure 11
NICE implementation plan



Source: Cambridge University Hospital NHS Foundation Trust

5

Conclusions

- 126** NICE guidance has a key role to play in ensuring that equitable and high-quality patient care is provided. However, implementation within the NHS is not undertaken on a systematic basis. Every NHS organisation has a responsibility to financially prepare themselves for the implementation of NICE technology appraisals, but despite the three-month direction and the available funding for technology appraisals, implementation is still not comprehensive and timely. Implementation rates for clinical guidelines among our participating organisations were lower.
- 127** A variety of factors affect the implementation of NICE guidance. Our research shows that the financial management arrangements an organisation has in place to support implementation are a key factor.
- 128** We have identified a general willingness to implement NICE guidance among NHS bodies and the introduction of the Healthcare Commission's Annual Health Check will add to the pressure for implementation. But there are a number of weaknesses in current arrangements. Lack of knowledge regarding the cost and savings of implementing NICE guidance and limited planning and monitoring are common features of current arrangements in most NHS bodies. Costs could be better controlled and implementation rates improved if appropriate planning, costing, budgeting and monitoring processes were in place at the local level among NHS bodies.
- 129** Our research found that lack of funding is perceived by NHS bodies to be the biggest barrier to implementation. While this may well be a factor, we found that a number of NHS bodies failed to assess the cost of implementing the guidance, and so were not in a position to make a judgement about whether they had sufficient funds to implement them. We also found that most NHS bodies failed to include the costs of implementing NICE guidance in their financial plans and that the actual implementation costs of NICE guidance were not routinely monitored. If implementation of NICE guidance is to improve and variations in care eliminated, there are a number of steps that NHS bodies can take to strengthen their approach to the financial arrangements associated with the implementation of NICE guidance.

- 130** NHS bodies are concerned about how PbR will affect the funding arrangements for implementing NICE guidance. Greater clarity is needed regarding the impact of PbR for both NHS trusts and PCTs, in particular, around whether the guidance falls inside or outside the tariff. Therefore, NHS bodies should familiarise themselves with the technical guidance on PbR issued by the DH. Furthermore, where funding for particular guidance is included within the tariff, providers should be held to account by commissioners to ensure that they are delivering the quality of care that has been paid for.
- 131** NICE will continue to support implementation through the work of its implementation team and will address the financial management angle through the production of cost templates for new technology appraisals and clinical guidelines.
- 132** At a local level, NICE guidance should be integrated into the mainstream financial management arrangements of NHS bodies if the levels of implementation are to increase. Financial planning, forecasting and budgeting for the implementation of NICE guidance all need to improve.
- 133** While recognising that the implementation of NICE guidance is challenging, the good practice demonstrated in this report highlights actions that trusts and PCTs can take locally to improve in this area.

Further information

For more information on the Audit Commission visit:

www.audit-commission.gov.uk

For more information on any aspect of NICE's work see the NICE website:

www.nice.org.uk

Appendix 1

Methodology

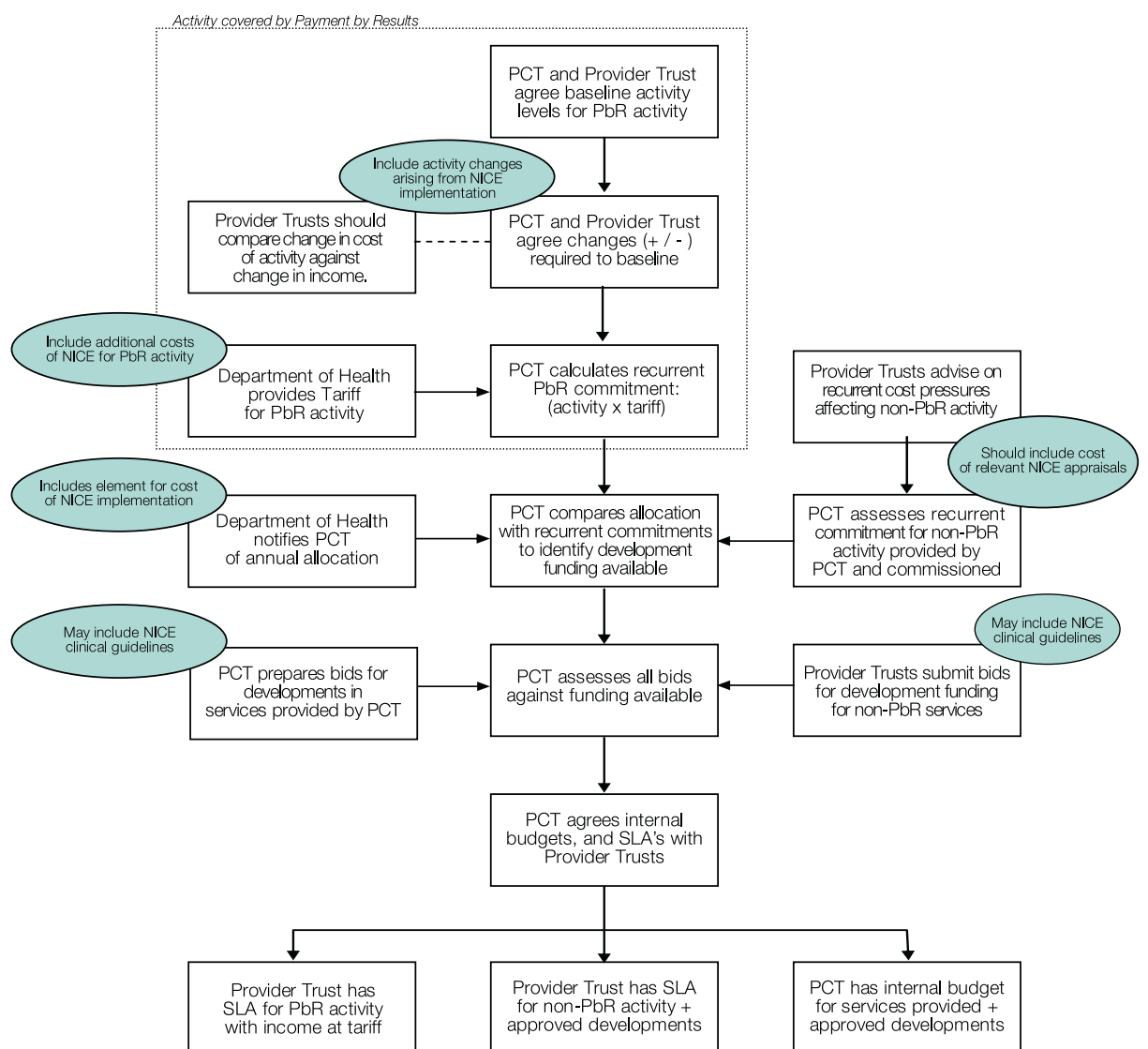
A web-based questionnaire was sent to the chief executives of 196 NHS bodies covered by a random sample of ten SHAs. The questionnaire was developed collaboratively between the Audit Commission and NICE to reflect the strategic objectives of the study. The Commission received replies from 71 respondents (a response rate of 36 per cent). The breakdown of identifiable respondents was: 27 PCTs, 23 acute trusts, 8 mental health trusts and four foundation trusts. A short email questionnaire was also sent to the chief executives of the ten SHAs, which was used to assess their performance management framework, reflecting their overarching performance management role in relation to the implementation of NICE guidance. We received two responses from the SHAs.

Prior to the mailing of the questionnaires, four sites were visited to serve as a pilot to validate the questionnaire for its usability and accuracy. These sites reflected the current diversity present in relation to the implementation of NICE guidance, which helped to further inform the scope of the questionnaire and identify pertinent issues for consideration.

The questionnaire covered general implementation, the financial management of clinical guidelines and technology appraisals and basic demographic data. Following a detailed analysis of responses, 16 respondents were selected for further in-depth case study interviews. The case studies selected reflected the diversity of implementation in relation to NICE guidance and varying financial managements processes associated with implementation. Site visits were undertaken at six acute trusts, six primary care trusts, two mental health trusts and two foundation trusts.

Appendix 2

How NICE should fit into funding decisions made by PCTs



Appendix 3

Business case pro forma

Introduction:

NICE number and title:

Date of Publication:

Clinical lead:

Managerial lead:

Outline the recommendations coming from the document.

Background:

Background information should include any information to assist in the understanding of the procedure/guidance or the use of the drug. Including:

- Prevalence and incidence of the condition
- Catchment population
- Changes to patterns of referrals that may arise from the guidance

Process:

Endeavour to describe:

- **What** is required to implement the procedure or prescribing of drugs
- **Who** will be responsible for administering/prescribing the procedure/drug
- **Where** it will be undertaken
- **How** the implementation will happen, and the arrangements required for ongoing management and care

Where there is both primary and acute care involvement with implementation, clearly state the responsibilities of each.

Implications:

If compliance is achieved with current practice, please supply evidence, such as an audit report.

If compliance is not yet achieved, consider what needs to happen to fully embrace the guidance.

Identify the implications to patients and the Trust if the guidance is not adopted.

Finance:

Consider the financial impact of the NICE document.

Can the requirements of the appraisal be absorbed into current practice?

If additional funding is required for implementation, clearly identify the additional costs which will be incurred:-

Cost description	WTE	Existing cost (£) (A)	Extra cost (£) (B)	Total cost (£) (A+B)
Direct costs				
<i>Medical staff</i>				
– Consultant				
– Other medical staff				
<i>Directorate pay costs</i>				
– Specialist nurse				
– Secretary				
– Administration				
– Other				
<i>Directorate non-pay costs</i>				
– Drugs				
– Med/Surg disposables				
– Stationery				
– Other				
Support costs (this section must be completed by the relevant department head)				
– Radiology				
– Pathology				

– Sterile Services
– Pharmacy
– Medical Physics
– Medical Records
– Ambulance Services
– Physiotherapy
– Occupational Therapy
– Speech Therapy
– Dietetics
– Other Support Costs
– Equipment Maintenance
– Capital charges
Total support costs (B)
Total all recurrent costs (A+B)

Capital costs	Cost
Specialist equipment	
Office/lab costs	
IT equipment	
Furniture	
Total capital cost	

(Note: identification of additional costs does not guarantee funding).

Signature of Finance Manager: _____ **Date:** _____

Signature of Implementation Lead: _____ **Date:** _____

Source: Cambridge University Hospital NHS Foundation Trust

Appendix 4

Costing template example

Example costing template

The following is from the Microsoft Excel template that accompanied the national costing report for lung cancer. It allows local costs to be calculated using data based on individual PCT populations and for variables to be amended to reflect local circumstances. The model has been designed to allow multiple PCTs to be combined to reflect local joint commissioning where applicable.

There is a clear positive association between deprivation and lung cancer incidence so this has been included in the model. Future templates may use other indicators of need, depending on applicability

Unit costs used

Where a national tariff price or indicative price exists for an activity then this has been used as the unit cost. The tariff has been increased by the national average market forces factor. The template provides the option to update unit costs to reflect local cost and it is suggested that the local tariff including local market forces factor is used.

Format of template

The template has three main sheets. The screen shot below shows the first sheet, which allows users to select their PCT(s). On the basis of the population, deprivation weighting and prevalence, the template will estimate the number of cases expected in the area.

Cost Impact of NICE Guideline on the diagnosis and treatment of lung cancer - England

Population Cost Assumptions Cost Summary Export Info

NHS National Institute for Clinical Excellence

Costing Populations

This template is used to calculate the cost impact of the lung cancer NICE guideline for designated populations; either single or aggregated PCT areas or a user defined population. When using the template please refer to the Costing Report for clarification on any assumptions.

1. Select the appropriate PCT area.

PCT area

	Model Value	User Defined
PCT Name	Adur, Arun and Worthing	
Population	217,316	217,316
Deprivation Weighting	0.836	0.836
Weighted Population	181,676	181,676

2. Edit the population and deprivation values by clicking the button on the right.

3. Add the user defined values to the Population chart below by clicking the button on the right.

	Name	Population	Deprivation Weighting	Weighted Population	Delete
1	Adur, Arun and Worthing	150,000	1.000	150,000	<input type="checkbox"/>
2					<input type="checkbox"/>
3					<input type="checkbox"/>
4					<input type="checkbox"/>
5					<input type="checkbox"/>
6					<input type="checkbox"/>
7					<input type="checkbox"/>
8					<input type="checkbox"/>
		150,000		150,000	

4. Repeat steps 1-3 to add up to 8 population areas or click NEXT to go to costing assumptions sheet

Send Feedback and Suggestions about this template to: costing@nice.org.uk

Sheet two (shown below) allows users to alter the variables used in the national model to reflect local circumstances.

Cost Impact of NICE Guideline on the diagnosis and treatment of lung cancer - England

Costing Assumptions

5. Make any necessary alterations to costing assumptions (highlighted in blue) by clicking the buttons on the right.

6. Proceed to Cost Summary sheet to view cost summary sheet by clicking Next.

	National Population	Selected Population		↑ Edit Core Values
	Standard Assumptions	Standard Assumptions	Local Assumptions	
Prevalence in the population				
Prevalence of Lung Cancer (per 100,000)	62.12	62.12	62.12	↑
Population estimate (100,000s)	493.50	1.50	1.50	
Total cases	30658.00	93.19	93.19	
Assuming a proportion of cases are subject to care pathway				
Current estimate of cases subject to care pathway	85.0%	85.0%	85.0%	↑
Current numbers subject to care pathway	26059.30	79.21	79.21	
Assuming improved awareness increases numbers on care pathway				
Estimated proportion on care pathway	90.0%	90.0%	90.0%	↑
Estimated numbers subject to care pathway	27592.20	83.87	83.87	
PET Scanning				
Current proportion receiving PET Scans	2.0%	2.0%	2.0%	↑
Current number of scans undertaken	521.19	1.58	1.58	
Estimated proportion requiring PET Scans	30.0%	30.0%	30.0%	↑
Estimated number of scans required	8277.66	25.16	25.16	
Increased number of scans	7756	24	24	
Cost per scan (weighted average)	£971	£971	£971	
Cost to undertake additional PET scans	£7,531,076	£23,304	£23,304	
Current proportion undergoing surgery	9.0%	9.0%	9.0%	

Finally, a third sheet summarises the results for users, as shown below:

Cost Impact of NICE Guideline on the diagnosis and treatment of lung cancer - England

Population Cost Assumptions Cost Summary Export Info

NHS National Institute for Clinical Excellence

Costing Summary

The annual revenue costs of changes arising from implementing the guideline are summarized below for the national population and for the selected PCT population(s). Two sets of PCT costs are shown below; one shows the costs incurred following the standard assumptions included in the cost report, the other shows the costs incurred after local assumptions are take into account.

	National Population Standard Assumptions	Selected Population Standard Assumptions	Local Assumptions
Revenue cost to undertake additional PET scans	£7,531,076	£23,304	£23,304
Cost of futile surgery avoided	-£869,538	£0	£0
Net cost of PET Scanning	£6,661,538	£23,304	£23,304
Savings from reduction in Bronchoscopies	-£1,465,239	-£4,527	-£4,527
Increased cost of CT scans	£291,872	£896	£896
Net saving from undertaking CT Scans first	-£1,173,367	-£3,631	-£3,631
Increased cost of Lung Cancer Nurses	£2,010,608	£6,078	£6,078
Savings from reduction in non-CHART regimes	-£1,325,610	-£4,290	-£4,290
Increased cost of CHART	£3,632,744	£10,942	£10,942
Net cost of introducing CHART	£2,307,134	£6,652	£6,652
Increased cost of chemotherapy following resection	£2,865,759	£7,683	£7,683
Increased cost of chemotherapy	£11,188,406	£34,007	£34,007
Reduced cost of radiotherapy	-£614,332	-£1,604	-£1,604
Net cost of changing regimes	£10,574,074	£32,403	£32,403
Grand Total	£23,245,746	£72,490	£72,490

In addition to the revenue costs there is significant capital expenditure required to increase access to PET scanning facilities. This is estimated nationally to be in excess of £50 million with 25% of the anticipated workload being related to lung cancer. There will also be some non-recurrent costs to recruit and train staff such as lung cancer nurses.

Send Feedback and Suggestions about this template to: costing@nice.org.uk

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